K121430
Pg 1 of 3

Section 5.0 510(k) Summary

MAR 1 2013

Name:	Cook Ireland Ltd
Address:	O'Halloran Road National Technology Park Limerick, Ireland
Phone:	011 353 61 334440
Fax:	011 353 61 239293
Contact Persons:	Jacinta Kilmartin, Regulatory Affairs Specialist Sinead Burke, Regulatory Affairs Manager

Date:	May 11, 2012
Trade Name:	Evolution® Biliary Stent System
Common Name:	Biliary Stent System
Classification Name:	Catheter, biliary, diagnostic (21 CFR 876.5010, Product Code: FGE)
Predicate Devices:	Boston Scientific Wallflex™ Biliary RX Stent System (Uncovered) (K061231 and K081733) and the Wallstent™ RX Biliary Endoprosthesis Stent System (Uncovered) (K012752 and K030107).
Description of the Device:	Stent Description: This flexible, self-expanding stent is constructed of nitinol wire with a radiopaque core. Both ends of the stent have an increased diameter called flanges intended to provide resistance to migration. The total length of the stent in its collapsed state is indicated by radiopaque markers on the inner catheter assembly. The stent is provided in either of two body diameters 8mm or 10mm and in the following lengths 4, 6, 8 or 10cm

Stent Delivery System Description:
The stent is mounted on an inner catheter, which accepts a 0.035" wire guide and is constrained by an outer sheath. A pistol-grip delivery handle allows stent deployment or recapture. The introducer sheath diameter is 8.5Fr and the working length is 200cm.

Indications for use: This device is used in palliation of malignant neoplasms in the biliary tree.

Comparison of Characteristics: The Evolution® Biliary Stent System is substantially equivalent to the currently marketed predicate devices, Boston Scientific Wallflex™ Biliary RX Stent System (Uncovered) (K061231 and K081733) and the Wallstent™ RX Biliary Endoprosthesis Stent System (Uncovered) (K012752 and K030107).
The proposed device shares many technological characteristics with at least one of the predicate devices (or fall within the range of predicates) in terms of the following:

- Stents:
  - Materials,
  - Stent type,
  - Stents supplied preloaded on the stent delivery system,
  - Ability to be visualised under fluoroscopy,
  - Dimensions,
  - Intended for permanent implantation,
  - Expanded stent ends.
- Stent Delivery System:
  - Allows placement using fluoroscopic and endoscopic techniques,
  - Allows deployment using a coaxial catheter system,
  - Wire guide port on outer sheath,
  - Compatibility with 0.035" wire guides,
  - Allows stent recapture during the deployment process.
- Intended Use.
- All are intended for single use only and are supplied sterile

	Differences include different stent delivery system materials and dimensions.
Performance Data:	Performance (bench) testing was carried out to determine the equivalence of the Evolution® Biliary Stent System to the predicate devices and to verify the safety and effectiveness of the device. **Performance Testing-Bench:** The bench testing was conducted in accordance with various applicable ASTM standards and in accordance with FDA's *Guidance for the Content of Premarket Notifications for Metal Expandable Biliary Stents.* The following bench tests were carried out: deployment, expansion force, compression force, dimensions, corrosion, joint strength, MRI and shelf life testing. The bench testing was successfully completed. Results of the testing provide reasonable assurance that the Evolution® Biliary Stent System will function as intended. **Biocompatibility:** Biocompatibility testing in compliance with ISO 10993-1 and FDA's *Guidance for the Content of Premarket Notifications for Metal Expandable Biliary Stents* supports the safety of the Evolution® Biliary Stent System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 1, 2013

Cook Ireland, Ltd.
% Ms. Jacinta Kilmartin, Regulatory Affairs Specialist
O'Halloran Road
National Technology Park
LIMERICK
IRELAND

Re: K121430
Trade/Device Name: Evolution® Biliary Stent System
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: February 22, 2013
Received: February 25, 2013

Dear Ms. Kilmartin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Christy L. Foreman

Christy Foreman
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121430

Device Name: Evolution® Biliary Stent System

Indications For Use: This device is used in palliation of malignant neoplasms in the biliary tree

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
2013.02.26 18:46:00 -05'00'

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121430